



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2022-0011]

Availability of FSIS Ready-To-Eat Fermented, Salt-Cured, and Dried Products Guideline

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Notice of availability and request for comments.

SUMMARY: FSIS is announcing the availability of and requesting comments on a guidance document for small and very small meat and poultry establishments manufacturing ready-to-eat (RTE), shelf-stable, fermented, salt-cured, and dried meat and poultry products, that do not use cooking as the primary lethality step. This guideline addresses many commonly asked questions concerning the food safety hazards associated with these products and the key steps in each process needed to ensure safety. This guideline replaces and expands upon information previously found in other guidance documents addressing the safe production of RTE fermented meat and poultry products.

DATES: Submit Comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: A downloadable version of the guideline is available to view and print at <https://www.fsis.usda.gov/policy/fsis-guidelines>. No hard copies of the guideline have been published.

FSIS invites interested persons to submit comments on this guideline. Comments may be submitted by one of the following methods:

- **Federal eRulemaking Portal:** This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow the online instructions at that site for submitting comments.

- **Mail:** Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250-3700.

- **Hand- or courier-delivered submittals:** Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350-E, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2022-0011. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

Docket: For access to background documents or comments received, call (202) 937-4272 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 937-4272.

SUPPLEMENTARY INFORMATION:

Background

FSIS is announcing the availability of a guidance document that addresses the safe production of products that rely on multiple hurdles, other than cooking alone, to achieve lethality and shelf-stability, and provides an overview of the scientific support available for these processes. For these types of products, no single step, such as cooking, is responsible for achieving adequate lethality of pathogens. Rather, a combination of processing steps such as fermentation, salt-curing, and drying are used to kill bacteria and prevent their outgrowth during storage. Many of these processing steps use a combination of factors or hurdles, such as reduction of pH, a high brine or salt concentration, or reduction of water activity (also referred to as a_w) over time.

FSIS addressed fermentation and drying previously in *Food Safety Lessons Learned from the Lebanon Bologna Outbreak*. This document addressed problems FSIS identified through an investigation of a 2011 foodborne illness outbreak of *E. coli* O157:H7 associated with Lebanon bologna. FSIS is removing that document from its web page and has incorporated information from that document into this guideline because information from the

earlier document can be applied to other semi-dry fermented products.

FSIS has also incorporated into the new guideline additional information related to drying. This information addresses the production of other fermented products, such as salami that is fermented and dried and salt-cured and dried products, as well as those products that rely on drying alone such as biltong.

This guideline also provides information on which fermented, salt-cured, and dried products are considered RTE. FSIS considers a product to be RTE if there is a standard of identity in 9 CFR part 319, defining it as fully cooked (e.g., hotdogs or barbecue meats) or if it meets the definition for a RTE product in 9 CFR 430.1, that is, one that is edible without further preparation for safety.

Not all products described in this guideline are RTE when the traditional production process is followed. Often additional hurdles, such as antimicrobial interventions or a low-temperature heat step, need to be applied along with compliance with the requirements in 9 CFR part 430 to make the product safe for consumption without further preparation. Many of the products described in this guideline (e.g., pepperoni, salami, bresaola, biltong, and droëwors) while not required by standard of identity to be RTE, are typically considered to have an intended use of RTE because marketing materials and recipes commonly identify them to consumers as RTE. Other products such

as basturma and country cured ham may be classified as RTE or not-ready-to-eat (NRTE) by the establishment. As the guidance explains, if an establishment identifies the intended use as NRTE for products such as pepperoni, salami, bresaola, biltong, and droëwors where the intended use is typically RTE, the establishment must have on-file documentation supporting their decisions (9 CFR 417.5(a)(1)). This support must address how the establishment can ensure the consumer will properly cook the product (9 CFR 417.5(a)(1)), particularly if there is evidence such as marketing materials or recipes commonly indicating the product is RTE. For example, if an establishment produces biltong as NRTE then it must demonstrate how it ensures consumers will safely prepare the product, given it is sometimes marketed as a teething toy for babies and as an on-the-go snack.

This guideline reiterates FSIS' recommendations that the lethality treatment of RTE shelf-stable meat and poultry products should achieve at least a 5.0-log₁₀ reduction of *Salmonella* and at least a 5.0-log₁₀ reduction for Shiga Toxin-producing *Escherichia coli* (STEC) (including *E. coli* O157:H7) for products containing beef as recommended in the *Cooking Guideline for Meat and Poultry Products (Revised Appendix A)*.¹ In addition to *Salmonella*, FSIS recommends the lethality treatment of RTE shelf-stable meat and poultry products should achieve at least a 3.0-log₁₀ reduction in *Listeria Monocytogenes* (Lm), although a 5.0-log₁₀ reduction or greater is desirable for

¹See: <https://www.fsis.usda.gov/guidelines/2021-0014>.

providing an even greater safety margin for ensuring that *Lm* does not grow to detectable levels during storage, as also recommended in the *FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments*.²

Establishments may use scientific support to demonstrate that the lethality treatment of fermented/acidified, salt-cured, and dried RTE products achieve at least a 5.0- \log_{10} reduction in *Salmonella* without demonstrating specific reductions in STEC (for products containing beef) and *Lm*, as indicated in the FSIS Hazard Analysis and Critical Control Point (HACCP) Systems Validation Guideline.³ However, research has shown that STEC (including *E. coli* O157:H7) and *Lm* are more tolerant than *Salmonella* during the fermentation and drying steps of dry/semi-dry fermented sausages,⁴ and *Lm* is more tolerant than *Salmonella* during the drying step of dried and salt-cured meat and poultry products.⁵ Therefore, if an establishment's scientific support is only based on reductions in *Salmonella* and the establishment has a STEC or *Lm* positive either through its own testing or FSIS' testing or is associated with an outbreak of these pathogens, the Agency would require the establishment, as part of its corrective actions, to validate that its food safety system effectively addresses STEC and *Lm* as intended, unless it can

² See: <https://www.fsis.usda.gov/guidelines/2014-0010>.

³ See: <https://www.fsis.usda.gov/guidelines/2015-0011>.

⁴ See: Hussein, et al., 2022; Ihnot et al., 1998; Porto-Fett et al., 2010; McKinney, 2019.

⁵ Porto-Fett et al., 2010; Reynolds et al., 2001.

support the cause of the positive was post-lethality contamination.

The guideline also addresses contributing factors in two *Salmonella* outbreaks involving RTE, fermented, and dried Italian-style meat products that occurred in 2021. The products were produced using multiple interventions (i.e., fermentation and drying) to control *Salmonella*. FSIS found that while the outbreak establishments used several processing controls (degree hours parameters for *Staphylococcus aureus* control, a minimum number of drying days for *Trichinella* elimination, and a final water activity level for shelf stability), none of these processing controls were validated individually or in combination to achieve a 5-log reduction in *Salmonella*.⁶

NACMPI Recommendations

Finally, the guideline includes several recommendations made by the National Advisory Committee on Meat and Poultry Inspection (NACMPI) in response to a charge FSIS brought to the committee in 2020 on the Validation of Ready-to-Eat Shelf-Stable Multi-hurdle Lethality Treatments.⁷ Specifically, in response to the committee's recommendations, FSIS included a link to the Niche Meat Processors Assistance Network as a resource in the guidance document. FSIS also included a link to its HACCP Coordinator listing⁸ that the Agency updated in 2021 as NACMPI recommended. In response to another NACMPI recommendation, FSIS

⁶ See: https://www.fsis.usda.gov/sites/default/files/media_file/2022-04/FSIS-After-Action-Review-2021-07.pdf.

⁷ See <https://www.fsis.usda.gov/news-events/publications/2020-nacmpi-reports>.

⁸ See <https://www.fsis.usda.gov/contact-us/state-contacts>.

included guidance for products such as those that are salt-cured where the initial validation period may extend beyond 90 calendar days due to the nature of the process and the length of time it takes to implement the critical operational parameters that impact lethality. FSIS did not accept NACMPI's recommendations to allow establishments to "Combine the best possible combination of available scientific support documents that may not exactly match" or to "Use scientific support that demonstrates a less than 5.0-log reduction" as these were contributing factors in the 2021 outbreaks.

FSIS Verification Activities

FSIS is aware that some establishments may determine they do not have adequate scientific support for the effectiveness of their HACCP system upon reviewing the recommendations in the guideline. Therefore, before FSIS verifies that establishments have adequately validated their HACCP plans for these products, FSIS is giving establishments time to review the guideline, their hazard analysis, and scientific support to determine if it is adequate or to identify new support. Additional time will be provided to establishments to update their support unless they have a *Salmonella*, STEC, or *Lm* positive either through their own testing or FSIS' testing or are associated with an outbreak of these pathogens. FSIS will update instructions to inspection program personnel (IPP) and Enforcement, Investigation, and Analysis Officers (EIAOs) on how to verify lethality and stabilization processes at establishments producing RTE shelf-

stable fermented, salt-cured, and dried meat and poultry products that do not use cooking as the primary lethality step. The instructions will make IPP and EIAOs aware that establishments will have additional time to update their support if it is not adequate and will also include information for EIAOs when conducting outreach at establishments producing these products to provide technical assistance as part of the compliance assistance they provide.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>. FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices.

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Paul Kiecker,
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